



FDA VETERINARIAN

WHEN PET FOODS ARE DRUGS

The following information is taken from a presentation by CVM's David A. Dzanic, D.V.M., Ph.D., DACVM, at the American Veterinary Medical Association Convention in July 1993.

As the American consumer has become more conscious of health and the benefits of good nutrition, many "health claims" have appeared on product labels. And, since the pet food industry follows many of the same marketing strategies as human food producers, it is not surprising that many pet food labels also bear these types of claims.

The Food, Drug, and Cosmetic Act defines "food" as an article used for food or drink for man or other animals. A "drug" is in part an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. The Act requires that a drug be subject to an approval process prior to marketing. Foods are not required to have a premarket approval unless they are considered to be food additives.

The legal definitions of foods and drugs become intertwined when a food label bears a claim that consumption of the product will treat, prevent, or otherwise affect a disease or condition. In other words, it makes a drug claim. And, if the product was not subject to the normal premarket clearance mechanism to demonstrate safety and efficacy, it is unsafe by definition. Therefore, pet foods with labels bearing drug claims are subject to regulation as drugs as well as foods.

The Nutrition, Labeling and Education Act (NLEA), passed in 1990, allowed certain health claims on foods for human consumption. These are claims where the intake of certain foods reduces the risk of a disease. For example, the relationship of dietary fiber with the reduction of risk of colon cancer could appear on breakfast cereals high in fiber. Other relationships, such as calcium and osteoporosis, and salt and hypertension, are also mentioned in the NLEA. Such claims, where the discussion of intake of a certain food with the reduction of risk of a disease, could appear on the label without automatically rendering the product a drug.

A similar relationship between diet and disease can be argued for pet foods; however, the NLEA did not expressly include animal feeds or pet foods in the new law. Thus, there is little legal basis to allow for similar health claims on pet food labels.

CVM has incorporated some of the philosophy of the NLEA in its policies to allow for meaningful health-related information on pet food labels. Much of these efforts to date have focused on label claims related to cat foods and the prevention of Feline Urologic Syndrome (FUS).

The exact cause of FUS is not known, but a number of dietary and non-dietary factors may be involved. The ability for a cat food to produce an appropriately acidic urine, and to a lesser degree, to limit the amount of dietary magnesium, may affect the incidence of the disease.

Label claims to prevent or reduce the risk of FUS, cystitis, or urinary problems are not allowed under the law. However, CVM, in an attempt to get related information to the consumer, is exercising regulatory discretion in allowing such claims as “reduce urine pH to help maintain urinary tract health,” or “low magnesium levels.” Of course, with respect to urine pH claims, this discretion is contingent on adequate controlled studies to demonstrate that the product produces an acidic urine and that it is safe for the animal. The “low magnesium level” claim requires the company to submit the results of proximate analysis of a number of runs of the product. The criteria to support a “low magnesium” claim is less than 0.12 percent on a dry matter basis and less than 25 mg per 100 kilocalories of metabolizable energy.

Another FUS claim, “low ash,” is not allowed on pet food labels. The current scientific consensus is that ash, per se, is not related to the incidence of FUS, and to reference it on the label would be false and misleading.

Weight Control Claims

More and more “lite” pet food products are now available, again following marketing practices for human foods. Some pet food labels have claimed that the product treats or prevents conditions associated with obesity, such as heart disease, arthritis, and even cancer.

The data to support the premise that obesity in dogs or cats causes these conditions is arguable. Regardless, such claims are drug claims and should not appear on pet food labels.

The Association of American Feed Control Officials (AAFCO) Pet Food Committee did establish an internal guideline that a “lite” product must be at least 15 percent lower in calories than the company’s standard product. However, since caloric content of pet foods varies greatly from company to company, one company’s “lite” could be higher in calories than another company’s standard product.

The AAFCO is developing means to allow caloric content statements on labels, and to define the term “lite” based on a standard reference for all products, regardless of manufacturer.

Dental Health Claims

Label claims for “clean teeth” have been on pet foods for many years, particularly on dry, hard, biscuit products. However, as the field of veterinary dentistry has grown, a number of products have borne more explicit claims—claims to treat or prevent gingivitis or periodontal disease. To achieve these intended effects, ingredients historically not found in foods are being incorporated in some new products. Ingredients such as pyrophosphates and enzymes are of concern to CVM. An ingredient that is not generally recognized as safe (GRAS) and not the subject of an approved food additive petition for its intended use may be an unapproved food additive. Therefore, even

without drug claims, pet food products containing unapproved food additives are subject to regulatory action.

Claims to treat or prevent gingivitis or periodontal disease are obviously drug claims and should not appear on pet food labels.

Veterinary Medical Foods

Veterinary medical foods are generally intended to be offered as the sole source of nutrition to animals with specific medical conditions. They usually contain restricted amounts of certain nutrients to aid in the mitigation of some disease process. These products are often identified on the market by the label phrase “use under directions of a veterinarian.” Originally, this phrase applied to labels for medicated pet foods, which contain an antibiotic or other drug. These products undergo the same premarket approval process as required for other drugs. In contrast, veterinary medical foods are regulated as foods and are not subject to the same controls as drugs.

Veterinary medical foods must substantiate adequacy by meeting the AAFCO nutrient profile or passing an AAFCO feeding trial protocol for adult maintenance, or include the phrase “for intermittent or supplemental use.” Since directions for use are presumed to be prescribed by the veterinarian, veterinary medical food labels are exempt from the requirement to include feeding directions.

Companies often establish the intended use of their veterinary medical food products through brochures, advertisements, or other promotional materials. CVM recognizes that since there are scientifically sound bases for use of these products in some cases of disease in dogs and cats, these products do serve a purpose. And, veterinarians obviously must be informed of indications, contraindications, and directions for use of the products. The same information distributed to the pet owner, however, is of more concern. Proper use of these types of products requires adequate veterinary supervision. An owner who feeds a product for its desired therapeutic effect solely on the basis of labeling or advertising claims may cause harm resulting from improper diagnosis or treatment.

Hypoallergenic Foods

Elimination diets, traditionally lamb and rice, for the diagnosis and management of food allergies in pets have been on the market for years as one form of veterinary medical food. There is nothing special or unique about these ingredients in terms of allergenicity. However, they were historically novel sources of protein since the use of these ingredients was uncommon in commercial dog foods, and pre-existing allergy to the ingredients would be unlikely.

Recently, many products containing lamb and rice have entered the consumer market, and many were labeled as “hypoallergenic,” or otherwise espoused the benefits of lamb and rice in the treatment or prevention of food allergies. This new marketing niche is detrimental in two aspects. The true nature and incidence of food allergies is clearly overemphasized and

misrepresented, and the novelty of lamb and rice is diminished, thus decreasing the usefulness of these ingredients in elimination diets.

DVM does not object to the use of lamb and rice in pet foods. If included in sufficient quantities, labels can list the presence of these ingredients. However, any claim to be “hypoallergenic” or any other claim of benefits beyond normal nutritive value is a drug claim.

Despite efforts to curtail drug claims, pet food products may be found on the market promoted for use to treat or prevent disease. Veterinarians and pet owners should recognize that such products may not have undergone any studies to establish safety or efficacy.

Please contact CVM if you have questions about the regulatory status of products or the validity of claims on pet food labels.